IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHEUSETTS

JOSHUA MYERS, Derivatively on Behalf of Nominal Defendant SESEN BIO, INC., Plaintiff, v. THOMAS R. CANNELL, D.V.M, JAY S. DUKER, M.D., JANE V. HENDERSON, CARRIE L. BOURDOW, and JASON A. KEYES, Defendants, And, SESEN BIO, INC., Nominal Defendant.	Case No.: 1:21-CV-11538 **VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Joshua Myers ("Plaintiff"), by and through his undersigned attorneys, brings this derivative complaint for the benefit of nominal defendant Sesen Bio, Inc. ("Sesen Bio" or the "Company"), against its Board of Directors (the "Board") and certain of its executive officers seeking to remedy defendants' breaches of fiduciary duties and violations of federal law. Plaintiff's allegations are based upon his personal knowledge as to himself and his own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff's counsel, including a review of publicly available information, including filings by Sesen Bio with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record.

NATURE AND SUMMARY OF THE ACTION

1. This is a shareholder derivative action that seeks to remedy wrongdoing committed by Sesen Bio's directors and officers in their management and control of the Company from

December 21, 2020 to the present ("Relevant Period").

2. Sesen Bio is a late-stage clinical company that purports to advance targeted fusion protein ("TFP") therapeutics for cancer treatments. Its most advanced product candidate is Vicineum (VB4-845), a locally administered TFP developed as a treatment of bacillus Calmette-Guérin ("BCG")-unresponsive non-muscle invasive bladder cancer ("NMIBC"). Sensen Bio reported preliminary efficacy data from its ongoing Phase 3 clinical trial for Vicineum, the VISTA trial, in August 2019.

3. On December 21, 2020, the Company announced that it had submitted its Biologics License Application ("BLA") to the U.S. Food and Drug Administration ("FDA") for Vicineum for the treatment of BCG-unresponsive NMIBC.

4. On August 13, 2021, Sesen Bio announced that the FDA declined to approve its BLA for Vicineum in its current form. The FDA provided certain "recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality."

5. On this news, the Company's share price fell $2.80, or 57%, to close at $2.11 per share on August 13, 2021, on unusually heavy trading volume.

6. Then, on August 16, 2021, Sesen Bio further revealed that "it appears that [the Company] will need to do a clinical trial to provide the additional efficacy and safety data necessary for the FDA to assess the benefit-risk profile, which is the basis for approval." As a result, the Company expected that it could not resubmit its BLA until 2023.

7. On this news, the Company's share price fell $0.89, or 42%, to close at $1.22 per share on August 16, 2021, on unusually heavy trading volume.

8. Then, on August 18, 2021, the health and medicine news site STAT published an

article entitled "Sesen Bio trial of cancer drug marked by misconduct and worrisome side effects, documents show." Citing "hundreds of pages of internal documents" and "three people familiar with the matter," the article detailed that the clinical trial for Vicineum was "marked by thousands of violations of study rules, damning investigator conduct, and worrying signs of toxicity the company did not publicly disclose."

9. On this news, the Company's share price fell $0.20, or 13%, to close at $1.31 per share on August 18, 2021, on unusually heavy trading volume.

10. Throughout the Relevant Period, Defendants caused the Company to materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, the Company failed to disclose to the market: (i) that the Company's clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (2) that three of the Company's clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (3) that the Company had submitted the tainted data in connection with the BLA for Vicineum; (4) that the Company's clinical trials showed that Vicineum leaked out into the body, leading to side effects including liver failure and liver toxicity, and increasing the risks for fatal, drug-induced liver injury; (5) that, as a result of the foregoing, the Company's BLA for Vicineum was not likely to be approved; (6) that, as a result of the foregoing, there was a reasonable likelihood that the Company would be required to conduct additional trials to support the efficacy and safety of Vicineum; and (7) that, as a result of the foregoing, the positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331 in that this Complaint alleges a violation of federal law. This Court has supplemental jurisdiction over the state law claims asserted herein pursuant to 28 U.S.C. § 1367(a). This action is not a collusive one to confer jurisdiction on a court of the United States which it would not otherwise have.

3. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1401 because a substantial portion of the transactions and wrongs complained of herein occurred in this District, and the Defendants have received substantial compensation in this district by engaging in numerous activities that had an effect in this District.

PARTIES

Plaintiff

4. Plaintiff purchased shares of Sesen Bio stock and continues to hold his Sesen Bio stock currently.

Nominal Defendant

5. Nominal Defendant Sesen Bio is incorporated under the laws of Delaware with its principal executive offices located in Cambridge, Massachusetts.

Director Defendants

6. ***Defendant Thomas R. Cannell*** ("Cannell") was, at all relevant times, President, Chief Executive Officer ("CEO") and a Director of the Company at all relevant times.

7. ***Defendant Jay S. Duker, M.D.*** ("Duker") was, at all relevant times, a Director of the Company and Chairman of the Board since February 2020.

8. ***Defendant Jane V. Henderson*** ("Henderson") was, at all relevant times, a Director of the Company. Defendant Henderson is the Chairman of the Audit Committee.

9. ***Defendant Carrie L. Bourdow*** ("Bourdow") was, at all relevant times, a Director of the Company. Defendant Bourdow is a member of the Audit Committee.

10. ***Defendant Jason A. Keyes*** ("Keyes") was, at all relevant times, a Director of the Company. Defendant Keyes is a member of the Audit Committee.

11. Defendants Cannell, Duker, Henderson, Bourdow and Keyes are herein referred to as the "Director Defendants." Because of their positions with the Company, they possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Director Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Director Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Director Defendants are liable for the false statements pleaded herein.

Officer Defendants

12. ***Defendant Monica Forbes*** ("Forbes") was the Chief Financial Officer ("CFO") of the Company at all relevant times.

13. The Director Defendants and Defendant Forbes are collectively referred to herein as "Defendants".

THE AUDIT COMMITTEE CHARTER

14. The Audit Committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of, our registered public accounting firm;

- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports and other communications from such firm;

- ***reviewing and discussing with management and our independent registered public accounting firm (x) our annual and quarterly financial statements and related disclosures (including any interim financial statements to be included in our periodic disclosures filed with the SEC); (y) our earnings press releases; and (z) litigation or other legal matters that could have a significant impact on our financial results***;

- ***monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics***;

- overseeing our internal audit function;

- overseeing our risk assessment and risk management policies;

- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;

- meeting independently with our internal auditing staff, if applicable, and our independent registered public accounting firm and management;

- reviewing and approving or ratifying any related person transactions;

- preparing the audit committee report required by SEC rules; and

- conducting a periodic self-assessment of the audit committee and its charter.

(Emphasis added).

MATERIALLY FALSE AND MISLEADING STATEMENTS

15. On December 21, 2020, the Company announced that it had submitted a "completed Biologics License Application" to the FDA for Vicineum. In a press release, the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced submission of the completed Biologics License Application (BLA) to the FDA for Vicineum for the treatment of high-risk, BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC) on December 18, 2020.
>
> Within 60 days after receipt of the completed application, the FDA will issue a decision to the Company on the acceptance of the filing, and whether the BLA has

> received Priority Review (six-month target PDUFA date) under its existing Fast Track designation.
>
> The BLA is supported by the pivotal Phase 3 VISTA trial, which the Company believes demonstrates a strong benefit-risk profile. The BLA also includes positive chemistry, manufacturing and controls (CMC) data that the Company believes validates the analytical comparability between clinical and commercial supply "There remains a significant unmet need for high-risk NMIBC, and we believe the differentiated clinical profile of Vicineum will provide a best-in-class option for physicians and their patients," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our strong non-clinical and clinical data, in addition to our positive comparability data, give us confidence in the regulatory path forward. I would like to thank the entire Sesen Bio team and our regulatory and manufacturing partners for their tireless dedication in helping us to complete the BLA submission. We look forward to continuing our regulatory progress by submitting a Marketing Authorization Application in Europe, which we anticipate in early 2021."

16. On February 1, 2021, the Company announced that it had a "productive Application Orientation Meeting" with the FDA regarding the BLA for Vicineum. In a press release, the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today reported that on January 29, 2021 the Company participated in a productive Application Orientation Meeting with the FDA regarding its Biologic License Application (BLA) for Vicineum, for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC).
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> After the Company submitted its BLA to the FDA in December 2020, Sesen Bio was invited to participate in an Application Orientation Meeting, which is available in certain Center for Drug Evaluation and Research (CDER) review divisions, at the review team's discretion, for priority applications where early action is expected and/or desired. The objectives of an Application Orientation Meeting include familiarizing the FDA with application datasets, discussing scientific aspects including clinical risk-benefit, and establishing early communication between applicants and the FDA.
>
> "We are very pleased with the outcome of Friday's 90-minute meeting with the FDA," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio.
>
> "We continue to believe Vicineum has a favorable risk-benefit profile which positions it to be best-in-class, and we are encouraged by the high level of time and

> engagement the FDA has demonstrated toward our review. We look forward to continuing to work with the FDA to expeditiously bring Vicineum to the market."

17. On February 16, 2021, the Company announced that the FDA had accepted its BLA for Vicineum and granted priority review. In a press release, the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, announced today that the U.S. Food and Drug Administration (FDA) accepted for filing the Company's Biologics License Application (BLA) for Vicineum for the treatment of high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), and granted the application Priority Review. In addition, the FDA stated that it is not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum.
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> * * *
>
> With Priority Review, the anticipated target Prescription Drug User Fee Act (PDUFA) date for a decision on the BLA is August 18, 2021.
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> ***"We have been meeting with the FDA regularly for the past two years on the application for Vicineum***," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We understand the FDA's position and guidance very clearly and have found the review process to be collaborative and engaging. With these critical FDA decisions, we have reached an inflection point for the Company. In addition to a clear regulatory path forward, we have continued to strengthen our balance sheet in preparation for the potential launch of a product we believe represents a significant advancement over available therapies. We remain focused on the patient and our mission to save and improve lives and expect to continue to make progress around the world in the coming months." [Emphasis added].

18. On March 15, 2021, the Company announced its fourth quarter and full year 2020 financial results as well as "significant regulatory and commercial readiness progress" for Vicineum. In a press release, the Company stated:

> We continue to make tremendous progress on our regulatory path with potential US approval later this year," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Our talented and growing team is laser-focused on bringing a best-in-class treatment to the market that has the potential to improve patient outcomes while reducing healthcare costs. With a strong balance sheet and clear regulatory path forward in both the US and Europe, we are positioned to fully realize the potentially significant global opportunity for Vicineum. We expect 2021 to be a transformative year for Sesen Bio and the patients we serve." US and

European Regulatory

Update US:

- ***On February 12, 2021, Sesen Bio received notice from the FDA that the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC was accepted for filing as of February 16th and granted Priority Review.*** The FDA set an accelerated 6-month target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021 for a decision on the BLA. The FDA also stated that they are not currently planning to hold an advisory committee meeting to discuss the BLA for Vicineum. [Emphasis added].

* * *

Commercial Update

- In October 2020, Sesen Bio entered into an exclusive agreement with Cardinal Health for third-party logistics (3PL) and specialty pharmacy distribution services for Vicineum for the treatment of BCGunresponsive NMIBC in the US. As part of the agreement, Cardinal Health will provide comprehensive end-to-end 3PL, order-to-cash management and specialty pharmaceutical distribution services to Sesen Bio in support of commercialization in the US. In addition to Fujifilm and Baxter, the Cardinal Health relationship completes the selection of major supply chain partners in support of the commercial distribution of Vicineum, if approved. The Company believes that the supply chain will be ready to support the potential commercial launch of Vicineum with product supply available in Urology clinics by the fourth quarter of 2021.

19. Also on March 15, 2021, the Company filed its annual report on Form 10-K for the period ended December 31, 2020 (the "2020 10-K"), affirming the previously reported financial results. Regarding the safety and efficacy of Vicineum, the 2020 10-K purported to warn:

> ***If clinical trials of Vicineum for the treatment of BCG-unresponsive NMIBC fail to demonstrate safety and efficacy to the satisfaction of the FDA or other foreign regulatory authorities or do not otherwise produce favorable results, we may incur additional costs or experience delays in completing, or ultimately be delayed or unable to complete, the development and commercialization of Vicineum for the treatment of BCG-unresponsive NMIBC***.
>
> Before obtaining marketing approval from regulatory authorities for the sale of Vicineum for the treatment of BCG-unresponsive NMIBC, we must complete preclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of Vicineum in humans. Clinical testing is expensive, difficult

> to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing.
>
> The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. [Emphasis added].

20. The 2020 10-K further stated that Vicineum "may cause undesirable side effects" that could, among other things, prevent regulatory approval. Specifically, the 2020 10-K stated:

> ***Vicineum for the treatment of BCG-unresponsive NMIBC may cause undesirable side effects, serious adverse events or have other properties that could delay or halt clinical trials, delay or prevent its regulatory approval, limit the commercial profile of its labeling, if approved, or result in significant negative consequences following any marketing approva***l.
>
> Undesirable side effects or serious adverse events caused by Vicineum for the treatment of BCG-unresponsive NMIBC could cause us or regulatory authorities to interrupt, delay or halt respective clinical trials and could result in a restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities.
>
> There were no Grade 4 or Grade 5 serious adverse events that were considered by the clinical investigators to be related to Vicineum during the Phase 1 and Phase 2 clinical trials of Vicineum for the treatment of NMIBC BCG failures. There was one Grade 5 serious adverse event, or death, which was determined by the clinical investigator to be unrelated to Vicineum. The most common reported treatment related adverse events were an abnormally frequent passage of small amounts of urine, blood in the urine and painful urination, the majority of which were considered to be mild or moderate in severity. No patients discontinued treatment due to a Vicineum-related adverse event during the Phase 1 and Phase 2 clinical trials.
>
> As of the May 29, 2019 data cutoff date, in patients across all cohorts (n=133) of our Phase 3 VISTA Trial of Vicineum for the treatment of BCG-unresponsive NMIBC, 88% experienced at least one adverse event, with 95% of adverse events being Grade 1 or 2. The most commonly reported treatment-related adverse events were dysuria (14%), hematuria (13%) and urinary tract infection (12%) - all of which are consistent with the profile of bladder cancer patients and the use of catheterization for treatment delivery. ***These adverse events were determined by the clinical investigators to be manageable and reversible, and only four patients***

> ***(3%) discontinued treatment due to an adverse event. Serious adverse events, regardless of treatment attribution, were reported in 14% of patients. There were four treatment-related serious adverse events reported in three patients including acute kidney injury (Grade 3), pyrexia (Grade 2), cholestatic hepatitis (Grade 4) and renal failure (Grade 5). There were no age-related increases in adverse events observed in the VISTA Trial***.
>
> In addition, side effects and serious adverse events or further safety or toxicity issues that we may experience in our clinical trials or in post-marketing experience could lead to the FDA's or other comparable foreign regulatory authority's imposition of a REMS or other post-marketing obligations, which could hinder us from generating revenues or achieving profitability. ***Results of our clinical trials could reveal an unacceptably high severity and prevalence of side effects or serious adverse events. As a result, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of Vicineum for the treatment of BCG-unresponsive NMIBC. The related drug-side effects or serious adverse events in our clinical trials could affect clinical trial patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims***. [Emphasis added].

21. The 2020 10-K also contained certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Cannell and Forbes attesting to, among other things, the disclosure of all material facts.

22. On May 4, 2021, the Company issued a press release entitled "Sesen Bio Announces Commercial Launch Readiness Progress as the Company Approaches the Potential Approval and Launch of Vicineum":

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the expansion of its leadership team with the appointment of experienced commercial industry leader, Lisa LaMond, as Vice President, Sales and Corporate Systems. The Company also announced its engagement of leading contract sales organization (CSO), Syneos Health, for field sales support and execution in the US for Vicineum.

23. On May 10, 2021, the Company announced its first quarter 2021 financial results and a commercial launch readiness update for Vicineum in a press release, stating:

> **US:**

- ***In February 2021, Sesen Bio received notice from the FDA that the BLA for Vicineum was accepted for filing***. Along with the acceptance, the Company was granted Priority Review with a target PDUFA date of August 18, 2021 for a decision on the BLA. The FDA also stated that an advisory committee meeting was not currently planned to discuss the BLA.

* * *

Commercial Update

- ***The Company continues to build its commercial organization with key leadership appointments and a partnership with a leading contract sales organization (CSO), Syneos Health, as it prepares for the anticipated commercial launch of Vicineum in the US in 3Q 2021***. Sesen Bio has begun to hire key commercial roles and has entered into a partnership with Syneos Health who will provide speed and logistical support in the hiring and deployment of the sales force. The sales force will include 35 sales representatives across four regions to target approximately 2,000 high prescribers of BCG. [Emphasis added].

24. Also on May 10, 2021, the Company filed its quarterly report on Form 10-Q for the period ended March 31, 2021, affirming the previously reported financial results. The report incorporated by reference the risk factors included in the 2020 10-K and contained SOX certifications signed by Defendants Cannell and Forbes attesting to, among other things, the disclosure of all material facts.

25. On July 14, 2021, the Company announced that it had a "productive Late-Cycle Meeting" with the FDA. In a press release, the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that on July 13, 2021, the Company participated in a productive Late-Cycle Meeting with the U.S. Food and Drug Administration (FDA) regarding the Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) currently under Priority Review with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.
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> The Late-Cycle Meeting is held late in the BLA review process between members of the FDA review team and the applicant to discuss the status of the review. The

purpose of the meeting is to share information, discuss any substantive review items identified to date and to discuss the objectives for the remainder of the review. The meeting does not address the final regulatory decision for the application.

"We are very pleased with the outcome of the Late-Cycle Meeting and continue to feel encouraged by the level of engagement from the FDA in our ongoing discussions regarding the BLA for Vicineum," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We understand the FDA's position on the remaining review items and anticipate a successful resolution of these matters prior to the target PDUFA date. We remain focused on the patient and bringing a differentiated product to market that has the potential to improve patient outcomes while reducing overall healthcare costs."

Key Review Updates Include:

- The Company and the FDA discussed remaining questions related to manufacturing facilities inspection, product quality information requests and additional information related to chemistry, manufacturing and controls (CMC), and agreed upon a timeline for supporting information to be submitted.

- No Discipline Review letters have been issued to date.

- The FDA confirmed that there is no Advisory Committee meeting planned at this time.

- No issues related to risk management have been identified to date.

- No post-marketing requirements, including a confirmatory trial, have been identified as necessary at this time.

- The Company and the FDA discussed clinical trial and manufacturing postmarketing commitments required at this time.

- The FDA's review of the BLA is ongoing and the Company believes the BLA remains on track for an anticipated regulatory decision by August 18, 2021, the target PDUFA date.

26. On July 26, 2021, the Company announced "significant commercial progress" as it "approache[d] the potential approval and launch of Vicineum." In a press release, the Company stated:

> "We are thrilled to have this experienced commercial team on board at Sesen Bio to build capabilities as we approach the potential commercial launch of Vicineum in the US market," said Patricia Drake, chief commercial officer of Sesen Bio.
>
> "They have made incredible progress across the core functions of sales, marketing and market access. We also believe our network of Urology and Uro-oncology KOL speakers will play an integral role in allowing us to educate their peers about Vicineum, which we believe will be a new tool in their practices to serve a large unmet medical need in NMIBC."
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> The Company has completed the hiring of ~25 talented internal employees to support the Company cross-functionally, as well as the hiring of 34 of 35 sales representatives as part of the contract sales organization, which will be deployed across four customer-centric regions and will target approximately 2,000 high-prescribers of BCG to drive awareness, trial and adoption of Vicineum for the treatment of BCG-unresponsive NMIBC. If approved, promotional efforts will begin immediately, and the Company expects Vicineum product to be commercially available to physicians and patients in the fourth quarter of 2021.

27. On August 2, 2021, the Company announced that it had hired Amy Ponpipom as Vice President, Assistant General Counsel in anticipation of the approval of Vicineum. In a press release entitled "Sesen Bio Strengthens Leadership Team as the Company Approaches the Potential Approval and Launch of Vicineum," the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the expansion of its leadership team in support of the Company's transformation into a commercial-stage company with the hiring of Amy Ponpipom as Vice President, Assistant General Counsel. The Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC), the Company's lead program, is currently under Priority Review with the US Food and Drug Administration (FDA) with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.
>
> "I am delighted to have Amy join the team here at Sesen Bio," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "Her strong industry experience and deep expertise in commercialization activities will be invaluable as we continue to work toward our PDUFA date and the potential launch of Vicineum in the US. I am confident that Amy's knowledge and skills will enable us to execute a world-class launch in order to fulfill our mission to save and improve the lives of patients."

28. On August 9, 2021, the Company announced its second quarter 2021 financial results and "significant global progress" for Vicineum in a press release, stating:

> US:
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> • ***On July 13, 2021, Sesen Bio participated in a productive Late-Cycle Meeting with the FDA regarding the BLA for Vicineum for the treatment of BCG-unresponsive NMIBC.*** In the meeting, the FDA confirmed that there is no Advisory Committee meeting planned at this time, and that no post-marketing requirements, including a confirmatory trial, have been identified at this time. Also in the meeting, the Company and the FDA discussed remaining questions related to manufacturing facility inspections, product quality information requests and additional information related to chemistry, manufacturing and controls (CMC), and a timeline to submit additional supporting information was agreed upon. The Company believes it remains on track for an FDA decision on its BLA for Vicineum by the target PDUFA date of August 18, 2021. [Emphasis added].

29. Also, on August 9, 2021, the Company filed its quarterly report on Form 10-Q for the period ended June 30, 2021, affirming the previously reported financial results. The report incorporated by reference the risk factors included in the 2020 10-K and contained SOX certifications signed by Defendants Cannell and Forbes attesting to, among other things, the disclosure of all material facts.

30. On August 11, 2021, the Company announced that it had hired John Knighton as Vice President and Chief Compliance Officer in anticipation of the approval of Vicineum. In a press release entitled "Sesen Bio Strengthens Executive Leadership Team as the Company Approaches the Potential Approval and Commercial Launch of Vicineum," the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced the expansion of its executive leadership team in support of the Company's continued transformation into a commercial-stage company with the hiring of John Knighton as Vice President and Chief Compliance Officer, effective August 16, 2021. The Company's Biologics License Application (BLA) for Vicineum for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), the Company's lead program, is currently under Priority Review with the US Food and Drug Administration (FDA) with a target Prescription Drug User Fee Act (PDUFA) date of August 18, 2021.

> "At Sesen Bio, ***we believe a strong culture of compliance is a source of competitive advantage, because a thorough understanding of laws and regulatory guidance allows us to fully explore innovative commercial models and strategies***," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "This enables us to do the right thing while maximizing launch uptake of Vicineum. As we near our PDUFA date, I am confident that John's extensive experience in establishing compliance programs and enabling the implementation of innovative commercial model elements will further position us to execute a world-class launch." [Emphasis added].

31. The above statements identified in ¶¶ 15-30 were materially false and/or misleading and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, the Company failed to disclose to investors: (1) that its clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (2) that three of its clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (3) that it had submitted the tainted data in connection with the BLA for Vicineum; (4) that its clinical trials showed that Vicineum leaked out into the body, leading to side effects including liver failure and liver toxicity, and increasing the risks for fatal, drug-induced liver injury; (5) that, as a result of the foregoing, the Company's BLA for Vicineum was not likely to be approved; (6) that, as a result of the foregoing, there was a reasonable likelihood that the Company would be required to conduct additional trials to support the efficacy and safety of Vicineum; and (7) that, as a result of the foregoing, the positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

THE TRUTH BEGINS TO EMERGE

32. On August 13, 2021, the Company announced that the FDA declined to approve its BLA for Vicineum in its current form. The FDA provided certain "recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and

Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality." In a press release the Company stated:

> Sesen Bio (Nasdaq: SESN), a late-stage clinical company developing targeted fusion protein therapeutics for the treatment of patients with cancer, today announced that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) for Vicineum™ (oportuzumab monatox-qqrs) for the treatment of BCGunresponsive non-muscle invasive bladder cancer (NMIBC).
>
> The FDA has determined that it cannot approve the BLA for Vicineum in its present form and has provided recommendations specific to additional clinical/statistical data and analyses in addition to Chemistry, Manufacturing and Controls (CMC) issues pertaining to a recent pre-approval inspection and product quality.
>
> "We are deeply disappointed by this unexpected result, and it is an unfortunate day for patients suffering from BCG-unresponsive NMIBC," said Dr. Thomas Cannell, president, and chief executive officer of Sesen Bio. "We remain dedicated to our mission to save and improve the lives of patients by bringing new treatment options to patients, and we intend to work closely with the FDA to understand next steps." The Company plans to request a Type A meeting as soon as possible with the FDA to discuss the next steps that are needed before the application may be approved.

33. On this news, the Company's share price fell $2.80, or 57%, to close at $2.11 per share on August 13, 2021, on unusually heavy trading volume.

34. On August 16, 2021, the Company held a conference call to discuss the CRL with analysts and investors. During the call, Defendant Cannell revealed that "it appears that [Sesen Bio] will need to do a clinical trial to provide the additional efficacy and safety data necessary for the FDA to assess the benefit-risk profile, which is the basis for approval." The Company would request a Type A meeting with the FDA to discuss the study design, including the primary endpoints and the sample size, to provide sufficient information to assess the benefit-risk profile of Vicineum. As a result, the Company expected that it could not resubmit its BLA until 2023.

35. On this news, the Company's share price fell $0.89, or 42%, to close at $1.22 per share on August 16, 2021, on unusually heavy trading volume.

36. The above statements identified in ¶¶ 32, 34were materially false and/or misleading and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, the Company failed to disclose to investors: (1) that its clinical trial for Vicineum had more than 2,000 violations of trial protocol, including 215 classified as "major"; (2) that three of its clinical investigators were found guilty of "serious noncompliance," including "back-dating data"; (3) that it had submitted the tainted data in connection with the BLA for Vicineum; (4) that its clinical trials showed that Vicineum leaked out into the body, leading to side effects including liver failure and liver toxicity, and increasing the risks for fatal, drug-induced liver injury; and (5) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

THE TRUTH FULLY EMERGES

37. On August 18, 2021, before the market opened, STAT published an article entitled "Sesen Bio trial of cancer drug marked by misconduct and worrisome side effects, documents show." Citing "hundreds of pages of internal documents" and "three people familiar with the matter," the article detailed that the clinical trial for Vicineum was "marked by thousands of violations of study rules, damning investigator conduct, and worrying signs of toxicity the company did not publicly disclose." The article summarized:

> Sesen Bio, a small biotech company that developed the bladder cancer drug, spent all of this year telling investors that its treatment was on its way to approval. After the FDA rejected it, CEO Thomas Cannell, fielding analyst questions on a Monday morning conference call, deemed it "a very surprising turn of events."
>
> ***But Sesen's internal documents — which include safety reports, raw data, and communications between employees — suggest a seismic difference between the company's public statements and the realities of the drug's development***. They also lift the curtain on revelations that might have played a role in the decision of

regulators at the FDA, which, consistent with its practice in the case of rejected drugs, did not comment on its decision.

According to the documents, Sesen's drug, called Vicineum, has led to dangerous elevations in liver enzymes that are associated with organ failure and death, which the Cambridge, Mass., company did not mention in its filings with the Securities and Exchange Commission. ***The bladder cancer study, which enrolled about 130 patients, had more than 2,000 violations of trial protocol, including 215 classified as "major," according to company documents.*** The study's independent monitors reported three investigators to the FDA for particularly egregious violations, calling them issues of "serious noncompliance" that "placed subjects at risk of harm," according to the documents.

* * *

In a statement to STAT provided a day before the rejection, Sesen did not deny the protocol violations, the investigator misconduct, or the omission of a drug-related death in its 2018 presentation. The company said Vicineum was not associated with life-threatening elevations in liver enzymes, a claim that contradicts multiple internal documents.

"We are confident that we have fully disclosed all relevant data to the FDA," Sesen said. "We stand by the safety and efficacy data of Vicineum," the company said, and as to the accuracy of its public statements, "we stand by the integrity of our disclosures and affirm they are based on the best information we have at the time." [Emphasis added].

38. The STAT article further stated that Vicineum had led to "worrisome side effects," including "a serious risk for fatal, drug-induced liver injury."

Because that toxin, produced by the bacterium Pseudomonas aeruginosa, can be deadly if it reaches the liver, Vicineum has to be administered directly to the site of the cancer.

But data from Sesen's clinical trials suggested Vicineum was leaking out into the body, leading to worrisome side effects, according to internal company documents.

In clinical trials testing Vicineum against head and neck cancer, one patient died of liver failure, according to the documents, and another matched the criteria for a clinical rule of thumb called Hy's Law, meaning a patient is at serious risk for fatal, drug-induced liver injury. That risk is particularly serious in the eyes of the FDA, and it's the most common reason drugs are pulled from the market over safety, according to an agency guidance.

> A similar pattern emerged in Sesen's Phase 3 bladder cancer study, called VISTA. One patient met the criteria for Hy's Law, suggesting Vicineum led to serious liver toxicity, according to the documents. Another patient was diagnosed with life threatening, drug-induced liver failure, confirmed by biopsy, according to the documents.
>
> In its statement, Sesen said the company "thoroughly reviewed" data from VISTA and "confirmed there were no cases of Hy's Law based on the clinical criteria as stipulated by FDA guidance." In the head and neck cancer study, "the data showed some elevated liver enzymes that have not been determined to be cases of Hy's Law," Sesen said. Both claims are contradicted by company documents, including a clinical report concluding one patient "met the criteria for Hy's Law" and internal communications about a second patient in which one employee wrote "I agree this is a Hy's Law case."

39. The STAT article also revealed that the trials purportedly supporting the BLA were "plagued by serious investigator misconduct that threatened the integrity of the data."

> VISTA was also plagued by serious investigator misconduct that threatened the integrity of the data, according to documents. In 2017 and 2018, Copernicus, a firm Sesen hired to monitor its trial, found three doctors in the study were guilty of "serious noncompliance," "continued noncompliance," and actions that "placed subjects at risk of harm," according to reports sent to the FDA.
>
> Separately, one investigator had his clinic closed in 2017 after his hospital's disciplinary committee concluded he had engaged in "disgraceful, dishonorable, or unprofessional" behavior. A second investigator was found to be back-dating data, according to internal Sesen documents, casting serious doubt on any information gathered from his clinic. In each case, the company was advised that "the data from these affected centers cannot be used in any data analysis" submitted to the FDA, according to the documents. Despite that, Sesen included results from both sites in its application for Vicineum's approval, according to the documents.
>
> In its statement, Sesen did not deny any instances of investigator misconduct in VISTA and did not dispute that it submitted tainted data to the FDA. "We are confident that we have fully disclosed all relevant data to the FDA," the company said, adding that "great care was taken every step of the way to ensure patient safety."

40. On this news, the Company's share price fell $0.20, or 13%, to close at $1.31 per share on August 18, 2021, on unusually heavy trading volume.

DUTIES OF THE DIRECTOR DEFENDANTS

41. By reason of their positions as officers and/or directors of the Company, and because of their ability to control the business and corporate affairs of the Company, the Director Defendants owed the Company and its investors the fiduciary obligations of trust, loyalty, and good faith. The obligations required the Director Defendants to use their utmost abilities to control and manage the Company in an honest and lawful manner. The Director Defendants were and are required to act in furtherance of the best interests of the Company and its investors.

42. Each director of the Company owes to the Company and its investors the fiduciary duty to exercise loyalty, good faith, and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets. In addition, as officers and/or directors of a publicly held company, the Director Defendants had a duty to promptly disseminate accurate and truthful information regarding the Company's operations, finances, and financial condition, as well as present and future business prospects, so that the market price of the Company's stock would be based on truthful and accurate information.

43. To discharge their duties, the officers and directors of the Company were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the affairs of the Company. By virtue of such duties, the officers and directors of the Company were required to, among other things:

(a) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

(b) conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's business prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;

(d) remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiries in connection therewith, take steps to correct such conditions or practices, and make such disclosures as necessary to comply with federal and state securities laws;

(e) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state and local laws, and rules and regulations; and

(f) ensure that all decisions were the product of independent business judgment and not the result of outside influences or entrenchment motives.

44. Each Director Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Director Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Director Defendants were aware, or should have been aware, posed a risk of serious injury to the Company.

45. The Director Defendants breached their duties of loyalty and good faith by causing the Company to issue false and misleading statements concerning the business results and prospects of the Company. As a result, the Company has expended, and will continue to expend, significant sums of money related to investigations and lawsuits.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

46. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties by the Director Defendants.

47. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and retained counsel competent and experienced in derivative litigation.

48. During the illegal and wrongful course of conduct at the Company and to the present, the Board consisted of Defendants Cannell, Duker, Henderson, Bourdow and Keyes. Because of the facts set forth throughout this Complaint, demand on the Company Board to institute this action is not necessary because such a demand would have been a futile and useless act.

49. The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

50. The Director Defendants (or at the very least a majority of them) cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. For the reasons that follow, and for reasons detailed elsewhere in this

complaint, Plaintiff has not made (and should be excused from making) a pre-filing demand on the Board to initiate this action because making a demand would be a futile and useless act.

51. Each of the Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

52. Each of the Director Defendants authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

53. Additionally, each of the Director Defendants received payments, benefits, stock options, and other emoluments by virtue of their membership on the Board and their control of the Company.

Defendant Cannell

54. Because of his CEO management position with the Company, Defendant Cannell is not independent.

55. The Company provides Defendant Cannell with his principal occupation, and he receives handsome compensation for his services. Defendant Cannell was responsible for most of the false and misleading statements and omissions that were made, including those contained in the Company's SEC filings referenced herein, many of which he either personally made or signed off on.

56. Defendant Cannell is also a Defendant in the securities class actions entitled *Bibb v. Sesen Bio, inc., et al.*, Case 1:21-cv-07025 (S.D.N.Y.) and *Cizek v. Sesen Bio, inc., et al.*, *Sesen Bio, inc., et al.*, Case 1:21-cv-07025 (S.D.N.Y.) (S.D.N.Y.) (the "Securities Class Action") and faces a substantial likelihood of liability; therefore, demand on Defendant Cannell is futile.

Defendants Henderson, Keyes and Bourdow

57. Defendants Henderson, Keyes and Bourdow served as members of the Audit Committee during the Relevant Period. Pursuant to the Audit Committee Charter, the Audit Committee Defendants were responsible for, *inter alia*, the effectiveness of the Company's internal controls, the integrity of its financial statements, and aspects of risk management and legal and regulatory compliance that may affect the Company's financial reporting. Defendants Henderson, Keyes and Bourdow failed to ensure the integrity of the Company's internal controls, as they are charged to do under the Audit Committee Charter and to issue false and misleading financial statements with the SEC. Thus, Defendants Henderson, Keyes and Bourdow breached their fiduciary duties, are not disinterested, and demand is excused as to them.

Defendant Cannell and Keyes

58. Prior to joining the Company, Defendant Cannell served as Orexigen Therapeutics, Inc.'s Chief Operating Officer & President of Global Commercial Products from July 2016 to July 2018, and as its Chief Commercial Officer from March 2015 to June 2016.

59. Defendant Keyes has served as the Chief Financial Officer of Equillium, Inc. (Nasdaq: EQ) since March 2018. Prior to joining Equillium, Defendant Keyes was Executive Vice President and Chief Financial Officer of Orexigen Therapeutics, Inc. from June 2016 to February 2018 where he played a key role in setting the business and financial strategy for the global

commercialization of the product portfolio. Prior to his role as Chief Financial Officer, Defendant Keyes, held the position of Vice President, Finance at Orexigen from February 2015 to June 2016.

60. Defendant Cannell and Keyes have a long business relationship and either defendant would not sue the other. Thus, due to their past business relationship, Defendants Cannell and Keyes are not disinterested, and demand is excused as to them.

COUNT I

(Against Defendants Cannell and Forbes For Violations Of Sections 10(b) And 21D Of The Exchange Act)

61. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

62. The Company and certain officers of the Company are named as defendants in the Securities Class Action, which assert claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Actions for these violations of law, the Company's liability will be in whole or in part due to Defendants Cannell and Forbes willful and/or reckless violations of their obligations as officers and directors of the Company.

63. Moreover, through their positions of control and authority as officers of the Company, Defendants Cannell and Forbes were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of the Company, including the wrongful acts described in the Securities Class Actions and herein.

64. As such, Defendants Cannell and Forbes are liable under 15 U.S.C. § 78j(b), which creates a private right of action for contribution, and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f), which governs the application of a private right of action for contribution arising out of violations of the Exchange Act.

COUNT II

(Against The Director Defendants For Breach Of Fiduciary Duty)

65. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

66. The Director Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Director Defendants owed the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

67. The Director Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

68. The Director Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Director Defendants breached their fiduciary duties of loyalty and good faith by permitting the use of inadequate practices and procedures to guide the truthful dissemination of Company news to the investing public and to the Company's shareholders, allowing or permitting false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise failing to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

69. As a direct and proximate result of the Director Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

70. As a direct and proximate result of the Director Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate

image and goodwill. Such damage includes, among other things, costs associated with defending and/or settling securities lawsuits and governmental investigations, severe damage to the share price of the Company's stock, resulting in an increased cost of capital, and reputational harm.

COUNT III

(Against The Director Defendants For Waste Of Corporate Assets)

71. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

72. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the time period in issue. It resulted in continuous, connected, and ongoing harm to the Company.

73. As a result of the misconduct described above, the Director Defendants wasted corporate assets by, *inter alia*: (a) paying excessive compensation, bonuses, and termination payments to certain of its executive officers; (b) awarding self-interested stock options to certain officers and directors; and (c) incurring potentially millions of dollars of legal liability and/or legal costs to defend and/or settle actions addressing Defendants' unlawful actions.

74. As a result of the waste of corporate assets, the Director Defendants are liable to the Company.

75. Plaintiff, on behalf of the Company, has no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

A. Against all Defendants and in favor of the Company for the amount of damages sustained by the Company as a result of Defendants' breaches of fiduciary duties;

B. Directing the Company to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect the Company and its shareholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for shareholder vote resolutions for amendments to the Company's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before shareholders for a vote a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater shareholder input into the policies and guidelines of the Board;

C. Awarding to the Company restitution from Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by Defendants;

D. Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff demands a trial by jury on all issues so triable.

Dated: September 17, 2021

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